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10/693,360	10/24/2003	Shalaby W. Shalaby	SHA-46	2254

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LEIGH P. GREGORY
ATTORNEY AT LAW
PO BOX 168
CLEMSON, SC 29633-0168

EXAMINER	
SILVERMAN, ERIC E	
ART UNIT	**PAPER NUMBER**
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/22/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/693,360	SHALABY, SHALABY W.	
	Examiner	Art Unit	
	Eric E. Silverman, PhD	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *4-7,10-12,15,16 and 18-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,8,9,13,14 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1-22-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1 – 20 are pending in this action.

Election/Restrictions

Applicants' timely response to election/restriction requirement, filed 11/15/2006, is noted. Applicants' elected Group I, claims 1 – 17 without traverse, and the species of the copolyester of claim 3 without traverse. Applicant indicated that claims 1, 2, 8, 9, 13, 14, and 17 read on the elected Group and species, however, it is believed that claim 3 also reads on the elected species. As such, claims 1 – 3, 8, 9, 13, 14, and 17 are considered on the merits in this action, and claims 4 – 7, 10 – 12, 15, 16, and 18 – 20 are withdrawn as non-elected.

Claim Objections

Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim, namely claim 1. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In this case, claim 2 does not limit claim 1 but merely suggests future uses for the composition of claim 1. Since intended use is not afforded patentable weight, the claims are so similar that they both cover the same compositions.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 – 3, 8, and 9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 - 20 of U.S. Patent No. 6,462,169. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims recite compositions (absorbable sealants) comprising the polymers of the '169 patent. Since instant compositions do not require any other component other than the polymers of the '169 patent, instant claimed compositions are rendered obvious thereby.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13 and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a written description rejection.**

The specification does not have sufficient support for claimed segmented copolyester mixed with a "further polyether ester". The specification vaguely suggests that such a mixture could be accomplished, however, there are no details in the specification that convey Applicants' possession of such a mixture. Not a single example of a specific "further polyether ester" useable in the invention is provided. Not a single example of a mixture of a segmented copolyester and a "further polyesther ester" is provided. There is no instruction as to how such a mixture would be made. Tellingly, there is no discussion on what such a mixture might be used for in the context of the invention. There is no disclosure of why such a mixture would have any different properties than the segmented copolyester composition that is the thrust of the claimed invention. There is no discussion of what properties, beneficial or otherwise, such a mixture would have. The absence of such would lead the artisan to doubt that Applicants actually possessed the claimed mixture. In consideration of the absence of not merely one, but of *all* of the above elements, the disclosure does not show that Applicant actually possessed the claimed mixture. At best, the disclosure amounts to an intimation that such a mixture *might* have some use within the context of the claimed invention, and *might* be worth making for some vague and unstated reason for some property or properties that the mixture *might or might not* possess.

With respect to claim 14, as it applies to the elected species of drug (anti-coagulants), the artisan would not recognize that Applicants had possession of basic

anti-coagulants, nor would the artisan recognize that Applicants had possession of said anti-coagulants conjugated to the further polyether-ester. The specification does not reveal even one example of a basic anti-coagulant that is useable in this invention. A review of the art shows that those anti-coagulants known in the art have acidic, not basic, moieties. For instance, all of the anti-coagulants disclosed by Medline Database (see PTO 892) are acidic, as they contain acidic moieties such as phenols, sulphonic acids, and carboxylic acids. US 6,211,249 recognizes heparin and chondroitin sulphate as anti-coagulants (col. 36). These are also both acids, by virtue of containing an acidic sulphonic acid moiety. Considering what was known to the artisan, and the lack of information in the disclosure, the artisan would not understand that Applicant actually possessed the claimed basic anti-coagulants or any ionic conjugates thereof.

Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 – 3, 8, 9, 13, 14, and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite "segmented copolyester". This term is not recognized in the art, and is not defined in the specification. Absent a limiting definition in the specification, the artisan would not be appraised at the meaning of "segmented copolyesters" and thus would be unable to discern the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 – 3 are rejected under 35 U.S.C. 102(b) as being Tian et al., "Macromolecular Engineering of Polylactones and Polylactides. Synthesis of Star-Branched Aliphatic Polyesters Bearing Various Functional End Groups" in *Macromolecules*.

Tian teaches a composition comrprising a three-arm branched poly(capralactone-b-lactic acid) (page 4139 - 4140). This is understood to be a "segmented coplyester" as required by instant claims. The polymer is synthesized by a different method than that of instant product-by-process claim 3, however the resulting material is the same. Instant claim 3 achieves a star shaped block copolymer by using a polyhydroxy compound as an initiator for the ring-opening polymerization of a first monomer, and then extends the polymerization by adding a second monomer. The

resulting polymer will have an ester linkage between the "core" and the polymer chains. The star shaped block copolymer of the art is achieved by first making the block copolymer and then affixing the end-group thereof to a triacid chloride. The resulting polymer is identical, even so far as the resulting ester bond between the "core" (in the art the core is trimesic acid, whereas in the claims the "core" is defined by the unspecified polyhydroxy compound). This is important in showing that the polymers in the compositions of the art are identical to those of the claims, irrespective of the fact that the "core" of the claims is, before reaction with monomer, a polyhydroxy compound whereas the "core of the claims, before reaction with the polymer is a triacid chloride. The composition is said to be useful for materials requiring biodegradation without the release of toxic products (introduction). Methods of end-capping the polymers are also discussed. The molecular weight is greater than 5 kD (Table 1 and Table 2), and the heat of fusion and glass transition temperature are inherently commensurate with instant claims, since the same material will have the same properties.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Bennett et al "Initial Biocompatibility studies of a novel degradable polymeric bone substitute that hardens in situ" *Bone*.

Bennett teaches compositions comprising four-armed star polymers of poly(dioxanone-co-glycolide) (page 1035). These are deemed to read on the "segmented copolyesters" of instant claims.

Claims 1 – 3 are rejected under 35 U.S.C. 102(e) as being anticipated by US 7,097,907 to Bennet et al ('907 or the '907 reference).

The '907 reference teaches compositions comprising star polymers of dioxanone attached to a poly hydroxyl core of either mannitol or threitol (Examples 1 – 3). These read on the "segmented copolyesters" of claim 1 and 2. Note that although the process of making the polymer is different from instant claim 3, these polymers are identical to those made by the process of claim 3 wherein both the "reacted"(first) cyclic monomer and the "end-grafted" (second) cyclic monomer are p-dioxanone. Analogous glycolide and capralactone polymers are also made in a similar fashion (see examples 4 – 11). Compositions containing these polymers are used to coat the surfaces of devices (that is, as sealants). See claims 15 – 20 of '907.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8, 9 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tian in view of US 6,309,669 to Setterstrom et al.

The teachings of Tian are discussed above.

What is lacking is carboxylate side-groups.

Setterstrom teaches that when used in controlled release devices, the release rate of drugs from polymers such as lactides and glycolides can be controlled by end-capping (that is, introducing side-groups to the end of the polymers). Specifically, by blending a mixture of carboxylic acid end-caped polymer and ester end-capped

polymer, the release rate can be controlled as desired by the artisan (col. 92 – 93). Although the method of making these end-capped polymers is not taught, they polymers are understood to be identical to those made by the process of instant claim 9. Furthermore, Setterstrom teaches these to be useful in conjunction with anti-coagulant agents, as required by the elected species of instant claim 17 (claim 5 of Setterstrom).

It would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to make a composition of the polymers of Tian wherein some of the polymers had carboxylic acid side-groups. The motivation is that Setterstrom teaches that in polymers quite similar to those of Tian, such manipulation would allow the artisan to control the release profile of a drug from a matrix of the polymer. Since Tian teaches how to end-cap the polymers, and provides polymers with functional handles to support such end-capping, the artisan would enjoy a reasonable expectation of success.

Claims 8, 9, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over the '907 reference in view of Setterstrom.

The teachings of the '907 reference are discussed above.

What is lacking is carboxylate side-groups.

Setterstrom teaches that when used in controlled release devices, the release rate of drugs from polymers such as lactides and glycolides can be controlled by end-capping (that is, introducing side-groups to the end of the polymers). Specifically, by blending a mixture of carboxylic acid end-caped polymer and ester end-capped polymer, the release rate can be controlled as desired by the artisan (col. 92 – 93). Although the method of making these end-capped polymers is not taught, they polymers

are understood to be identical to those made by the process of instant claim 9. Furthermore, Setterstrom teaches these to be useful in conjunction with anti-coagulant agents, as required by the elected species of instant claim 17 (claim 5 of Setterstrom).

It would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to make a composition of the polymers of '907 wherein some of the polymers had carboxylic acid side-groups. The motivation is that Setterstrom teaches that in polymers quite similar to those of '907, such manipulation would allow the artisan to control the release profile of a drug from a matrix of the polymer. Since these manipulations are discussed in Setterstrom with polymers quite similar to those of '907, the chemistry used to make these manipulations to the polymers of '907 would be expected to be quite similar to that used in Setterstrom. Therefore the artisan would enjoy a reasonable expectation of success.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,211,249 teaches polyether esters, and that such are used for making medical devices. US 5,225,521, US 5,951,997, and US 5,713,920 all teach polymers with similar composition or architecture to those used in instant compositions. US 6,447,796 provides additional information about using carboxylic acids to end-cap lactide, glycolide, and related polymers. Helminen "Branched and crosslinked resorbable polymers based on lactic acid, lactide, and eta-caprolactone" provides data about the rheological properties of the type of polymers of instant claims and those cited

in the art, and supports the notion that the polymers of the art have the claimed properties.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571 272 8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric E. Silverman, PhD
Art Unit 1615

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600